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## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

nnlication of:

Jerome B. Zeldis

Confirmation No: 9742

Application No:

10/534,324

Group Art Unit: To Be Assigned

Filed:

May 5, 2005

Examiner: To Be Assigned.

For: METHODS OF USING AND

Jones Day Docket No.: 9516-086-999

COMPOSITIONS COMPRISING SELECTIVE CYTOKINE INHIBITORY DRUGS FOR THE

(CAM No.: 501872-999085)

TREATMENT AND MANAGEMENT OF MYELOPROLIFERATIVE DISEASES

## INFORMATION DISCLOSURE STATEMENTUNDER 37 C.F.R. §1.56 AND §1.97

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure imposed by 37 C.F.R. § 1.56 and §1.97 to inform the Patent Office of all references coming to the attention of each individual associated with the filing or prosecution of the subject application, which are or may be material to the patentability of any claim of the application, Applicant hereby directs the Examiner's attention to References A01-A66, B01-B08 and C01-C45, listed on the attached Substitute For form 1449/PTO entitled "Information Disclosure Statement by Applicant."

Copies of references B01-B08 and C01-C45 are submitted herewith. Copies of References A01-A65, being U.S. patents and U.S. publication documents are not submitted herewith pursuant to 37 C.F.R. § 1.98(a)(2)(ii). A copy of Reference A65, being a provisional application that is available at the USPTO's private PAIR system is not submitted herewith pursuant to 1287 OG 163.

Identification of the listed references is not to be construed an admission of Applicant or Attorneys for Applicant that such references are available as "prior art" against the subject application. Applicant respectfully requests that the Examiner review the foregoing references and that the references be made of record in the file history of the application.

This Information Disclosure Statement is filed under 37 C.F.R. §1.97(b) before the mailing of the first Office action on the merits. Therefore, no fee is believed to be due. Should any fee be required, however, please charge such fee to Jones Day Deposit Account No. 50-3013.

Respectfully submitted.

Date: March 3, 2006

Young/WoonReg. No.)

For: Anthony M. Insogna

52,042 35,203

JONES DAY

222 East 41<sup>st</sup> Street New York, New York 10017

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Enclosures



INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Use several sheets if necessary)

ATTY DOCKET NO. 9516-086-999	APPLICAT	ION NO.
(CAM No. 501872-999085)	10/534,324	
APPLICANT:		
Zeldis		
FILING DATE:	ART UNIT:	CONF. NO.:
May 5, 2005		9742

	U.S. PATENT DOCUMENTS					
EXAMINER'S INITIALS*		DOCUMENT NUMBER	DATE MM/DD/YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	
	A01	3,536,809	10/27/1970	Applezweig		
	A02	3,598,123	08/10/1971	Zaffaroni		
	A03	3,845,770	11/05/1974	Theeuwes et al.		
	A04	3,916,899	11/04/1975	Theeuwes et al.		
	A05	4,008,719	02/22/1977	Theeuwes et al.		
	A06	5,059,595	10/22/1991	La Grazie		
	A07	5,073,543	12/17/1991	Marshall et al.		
	A08	5,120,548	06/09/1992	McClelland et al.	*	
	A09	5,354,556	10/11/1994	Sparks et al.		
	A10	5,463,063	10/31/1995	Muller		
	All	5,591,767	01/07/1997	Mohr et al.		
	A12	5,605,914	02/25/1997	Muller		
	A13	5,632,984	05/27/1997	Wong et al.		
	A14	5,639,476	06/17/1997	Oshlack et al.		
	A15	5,643,915	07/01/1997	Andrulis, Jr. et al.		
	A16	5,658,940	08/19/1997	Muller et al.		
	A17	5,674,533	10/07/1997	Santus et al.		
	A18	5,698,579	12/16/1997	Muller.		
	A19	5,703,098	12/30/1997	Muller		
	A20	5,728,844	03/17/1998	Muller		
	A21	5,728,845	03/17/1998	Muller		
	A22	5,733,566	03/31/1998	Lewis		
	A23	5,736,570	04/07/1998	Muller		
	A24	5,770,589	06/23/1998	Billson		
	A25	5,801,195	09/01/1998	Muller et al.		
	A26	5,877,200	03/02/1999	Muller		
	A27	5,929,117	07/27/1999	Muller et al.		
	A28	5,968,945	10/19/1999	Muller et al.		
	A29	6,001,368	12/14/1999	Jenks		

EXAMINER	/Marcos Sznaidman/	DATE CONSIDERED	10/27/2008		
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and considered. Include copy of this form with next communication to applicant.					

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Substitute for Form 1449/PTO
INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use several sheets if necessary)

ATTY DOCKET NO. 9516-086-999 (CAM No. 501872-999085) 10/534,324

APPLICANT: Zelfdis

FILING DATE: May 5, 2005 ART UNIT: CONF. NO.:

## U.S. PATENT DOCUMENTS

EXAMINER'S INITIALS*		DOCUMENT NUMBER	DATE MM/DD/YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	A30	6,011,050	01/04/2000	Muller et al.	
	A31	6,015,803	01/18/2000	Wirostko	
	A32	6,020,358	01/04/2000	Muller et al.	
	A33	6,046,221	04/04/2000	Muller et al.	
	A34	6,075,041	06/13/2000	Muller	
	A35	6,130,226	10/10/2000	Muller et al.	
	A36	6,180,644	01/30/2001	Muller et al.	
	A37	6,200,987	03/13/2001	Muller	
	A38	6,214,857	04/10/2001	Muller et al.	
	A39	6,218,369	04/17/2001	Bombardelli et al.	
	A40	6,225,348	05/01/2001	Paulson	
	A41	6,262,101	07/17/2001	Muller et al.	
	A42	6,281,230	08/28/2001	Muller et al.	
	A43	6,284,780	09/04/2001	Muller et al.	
	A44	6,316,471	11/13/2001	Muller et al.	
	A45	6,326,388	12/04/2001	Man et al.	
	A46	6,429,221	08/06/2002	Muller et al.	
	A47	6,479,554	11/12/2002	Muller et al.	
	A48	6,518,281	02/11/2003	Muller et al.	
	A49	6,656,964	12/02/2003	Muller et al.	
	A50	6,667,316	12/23/2004	Man et al.	
	A51	6,844,359	01/18/2005	Muller et al.	
	A52	6,699,899	03/02/2004	Man et al.	
	A53	6,911,464	06/28/2005	Man et al.	
	A54	6,962,940	11/08/2005	Muller et al.	
	A55	2003-0045726	03/06/2003	Muller et al.	
	A56	2003-0114516	06/19/2003	Muller et al.	
	A57	2004-0006096	01/08/2004	Muller et al.	
	A58	2004-0019106	01/29/2004	Muller et al.	

EXAMINER	/Marcos Sznaidman/	DATE CONSIDERED	10/27/2008			
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.						

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EXAMINER'S INITIALS\*

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2004-0147588

2004-0167174

2004-0167199

2004-0204448

2004-0254214

WO 01/45702

WO 03/080048

U.S. PATENT DOCUMENTS					
BER	DATE MM/DD/YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear		
	07/29/2004	Man et al.			
	08/26/2004	Man et al.			
	08/26/2004	Muller et al.			
	10/14/2004	Muller et al.			

	A64	2005-0014727	01/20/2005	Muller et al.				
	A65	2006-0025457	02/02/2006	Muller et al.				
	A66	60/372,348	04/02/2002	Hariri et al.				
	-		FOREIGN	N D A TENTE DOCUMENTO		_		
			FOREIG	N PATENT DOCUMENTS				
EXAMINER'S INITIALS*		Country Code, Number, Kind of Code (If known)	DATE MM/DD/YYYY	Name of Patentee or Applicant of Cited Document			TRANSLATION	
						YES	NO	
	B01	WO 95/01348	01/12/1995	Celgene Corporation				
	B02	WO 97/08143	03/06/1997	Celgene Corporation				
	B03	WO 97/23457	07/31/1997	Celgene Corporation				
	B04	WO 99/06041	02/11/1999	Celgene Corporation				
	B05	WO 01/34606	05/17/2001	Celgene Corporation				

Celgene Corporation

Celgene Corporation

Man et al.

12/16/2004

06/28/2001

10/02/2003

WO 03/080049 10/02/2003 Celgene Corporation EXAMINERS NON PATENT LITERATURE DOCUMENTS (include name of the author (in CAPITAL LETTERS), title of the article (when INITIALS\* appropriate), title of the item (book ,magazine, journal, etc.,), date, page(s)s, volume, publisher, city and/or country where published., etc.) BAROSI et al., 2001, "Safety and efficacy of thalidomide in patients with myelofibrosis with myeloid metaplasia," Br. COL J. Haematol. 114(1):78-83 BENNETT AND PLUM, eds., 1996, Cecil Textbook of Medicine, 20th edition, W.B. Saunders Company, pp. 502-503, C02 BRAUNWALD et al., eds., 2001, Harrison's Principles of Internal Medicine, 15th edition, McGraw-Hill, pp. 701-703 C03 CANEPA et al., 2001, "Antitumor activity of thalidomide in idopathic myelofibrosis," Haematologica 86(11 C04 Suppl 1):12-14

EXAMINER	/Marcos Sznaidman/	DATE CONSIDERED	10/27/2008				
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.							

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Form 14	149/PTO	ATTY DOCKET NO. 9516-086-999 (CAM No. 501872-999085)	APPLICATION NO.	
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		May 5, 2005	9742	
approp	riate), title of the item (book ,magazine, journal, etc.,), dat			
core		nd secondary myelofibrosis," Br.	J. Haematol. 115(2):313-	
C03		as the lide mide and the lide mide on	alogues " Ann Phaum Die	
C06		y mandonnue and mandomide an	aiogues, Ann. Rheum. Dis.	
000		fylline (FTX) prevent the develoop	ment of chronic	
		ats without inhibiting its anti-tumor	al effect," Blood 92(10	
C07				
C08 chromosome," Science 247(4944):824-830  D'AMATO et al., 1994, "Thalidomide is an inhi		•		
				f thalidomide and its chemical and functional analogs," Crit. Rev.
		antiangiogenic therapy," Expert Opin. Biol. Ther. 2(8):953-966		
CIZ	EHRENPREIS et al., 1999, "Thalidomide therapy for p			
C13	Gastroenterology 117(6):1271-1277			
C14	through vascular inhibition," Cancer Res. 63(23):8073	3-8078	-	
1				
C16			of ICSBP inhibits Bcr-Abl-	
CIS			an multiple myslome calls	
C16	to conventional therapy," Blood 96(9):2943-2950			
C17			1. 22:165-242	
C18	KROPFF, 2000, Blood 96(11 part 1):168a, Abstract 7	25		
210		Philadelphia chromosome-positive leu	kemias," N. Engl. J. Med.	
C19		mia vera chronic myelocytic lauke	mia and muslofibrosis has	
C20 an increased vascularity," Am. J. Pathol. 157(1)				
CIL	MARRIOTT et al., 1998, "CC-3052: a water-soluble	analog of thalidomide and potent in	hibitor of activation-induced	
C21			nalogues." Expert Opin. Biol.	
C22	Ther. 1(4):1-8	•	•	
	MARRIOTT et al., 2002, "Thalidomide and its analog	ues have distinct and opposing effe	ects on TNF-alpha and	
C23	TNFR2 during co-stimulation of both CD4(+) and CD	08(+) T cells," Clin. Exp. Immunol.	130(1):75-84	
C24	Curr Drug Targets-Immune Endocr Metabol Discret	unomodulatory drugs (IM1Ds) as po 1-3/3):181-186	mential inerapeutic agents,"	
C24	MARTYRÉ, 1991, "Platelet PDGF and TGF-beta leve	els in myeloproliferative disorders.	Leuk, Lymphoma 6(1):1-6	
	NON P F appropriate	NON PATENT LITERATURE DOCUMENTS (include name of appropriate), title of the item (book, magazine, journal, etc.,.), data published, etc.)  CANEPA et al., 2001, "Thalidomide in agnogenic a Signature of CAREPA et al., 2001, "Thalidomide in agnogenic a Signature of Si	Form 1449/PTO  ON DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)  APPLICANT: Zelfdis  FILING DATE: May 5, 2005  NON PATENT LITERATURE DOCUMENTS (include name of the author (in CAPTAL LETTERS), appropriate), title of the item (book ,magazine, journal, etc.), date, pogets)s, volume, publisher, city an published, etc.)  CANEPA et al., 2001, "Thalidomide in agnogenic and secondary myelofibrosis," Br. 315  CORRAL, L.G. et al., 1999, "Immunomodulation by thalidomide and thalidomide and 58:Suppl D1107-1113  COSTA et al., 1998, "Thalidomide (TLD) and pentoxifylline (FTX) prevent the develop cardiomyopathy provoked by doxorubicin (DXR) in rats without inhibiting its anti-tumor Suppl. 1):235b, Abstract 4007  DALEY et al., 1999, "Induction of chronic myelogenous leukemia in mice by the P210 <sup>bcinit</sup> (2005) D'AMATO et al., 1994, "Thalidomide is an inhibitor of angiogenesis," PNAS USA 91:400  D'AMATO et al., 1994, "Thalidomide is an inhibitor of angiogenesis," PNAS USA 91:400  DD DEDGE et al., 2003, "Angiogenesis inhibitors in cancer therapy," Curr. Opin. Investig.  DREDGE et al., 2003, "Angiogenesis inhibitors in cancer therapy," Expert Opin. B. DREDGE et al., 2002, "Recent developments in antiangiogenic therapy," Expert Opin. B. BHRNPREIS et al., 1999, "Thalidomide therapy for patients with refractory Crohn's disease and forced covery and through vascular inhibition." Cancer Res. 5(323):8073-8078  HAO et al., 2000. "Expression of interferon consensus sequence binding protein (ICSBP Ab1-induced murine chronic myelogenous technic like disease, and forced coveryession inhibitor of an analogs overcome drug resistance of hundred myelogroliferative disorder, Mol. Cell. Biol. 20(4): 1149-1161  HIDESHIMA et al., 2000, "Thalidomide and its analogs overcome drug resistance of hundred myelogroliferative disorder," Mol. Cell. Biol. 20(4): 1149-1161  ROCH, 1985, "Thalidomide and one marrow in polycythemia vera, chronic myelogytic leuke an increased vascularity," Am. J. Pathol. 157(1):151-19  MARRIOTT et al., 2002,	

EXAMINER	/Marcos Sznaidman/	DATE CONSIDERED	10/27/2008				
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not							

MARX et al., 1999, "A phase I/II trial of thalidomide as an antiangiogenic agent in the treatment of advanced cancer," Proc. Am. Soc. Clin.Oncol. 18:454a

				Sheet 5 of 5	
Substitute for	Fa 1	MAD//TTO	ATTY DOCKET NO. 9516-086-999 (CAM No. 501872-999085)	APPLICATION NO.	
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			May 5, 2005	9742	
EXAMINER'S NON PATENT LITERATURE DOCUMENTS (include nam appropriate), title of the item (book ,magazine, journal, etc.,), published., etc.)					
	C27 McCANN, 1999, "Results of breast cancer drugs under spotlight," Drug Topics 41-42				
	C28 MOLLER et al., 1997, "Inhibition of IL-12 production by thalidomide," J. Immunol. 159(10):5157-5161				
	C29 MULLER et al., 1999, "Amino-substituted thalidomide analogs: potent inhibitors of TNF-alpha production, Med. Chem. Lett. 9(11):1625-1630				
	C30	inhibitory activity," J. Med. Chem. 39(17):3238-3240	halidomide produce analogs with enhanced tumor necrosis factor 240		
	C31	MULLER et al., 1998, "Thalidomide analogs and PDE4			
	C32	MUNSHI et al., 1999, "Peripheral blood stem cell, col newly diagnosed multiple myeloma (MM): Influence 1):578a, Abstract 2577			
	C33	PRUNERI et al., 1999, "Angiogenesis in myelodyspla	stic syndromes," Br. J. Cancer 81(8	3):1398-401	
	C34	RAJKUMAR, 2000, "Thalidomide in multiple myelor	na," Oncology (Williston Park) 14(	12 Suppl 13):11-16	
	C35	RAZA et al., 2001, "Thalidomide produces transfusion with myelodysplastic syndromes," <i>Blood</i> 98(4):958-96	55	•	
	C36 SCHANDENÉ et al., 2000, "Interferon alpha prevents spontaneous apoptosis of clonal Th2 cells associated with chronic hypereosinophilia," Blood 96(13):4285-4292				
	C37	SILVER, 1993, "Interferon-alpha 2b. A new treatmen			
	C38	SINGHAL et al., 1999, "Antitumor activity of thalidom 341(21):1565-1571			
	C39	TEFFERI et al., 1994, "Issues in the diagnosis and man- 69(7):651-655	•	•	
	C40	TICDNEY and all 1000 C IN I' ID:	and the same	1 . 0 7 . 100 000	

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EXAMINER	/Marcos Sznaidman/	DATE CONSIDERED	10/27/2008
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VACCA et al., 2001, "Angiogenesis in hematologic malignancies," Haematol. 86(11 Suppl 1):1-5

WOLFF, ed., 1995, Burger's Medicinal Chemistry and Drug Discovery, 5th ed:172-178, 949-982

Crohn's disease," Gastroenterology 117(6):1278-1287

The Merck Manual, 1987, 15th ed 1:922-924

Physician's Desk Reference, 2002, 56th ed., pp. 1154-1158; 1755-1760

VASILIAUSKAS et al., 1999, "An open-label pilot study of low-dose thalidomide in chronically active, steroid-dependent